Genetics Task Force Working Glossary

Anonymous
Unidentified/unidentifiable.

The National Bioethics Advisory Committee describes anonymous biological material as "*Unidentified specimens:* For these specimens, identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved by the repository." And "*Unidentified samples:* Sometimes termed "anonymous," these samples are supplied by repositories to investigators from a collection of unidentified human biological specimens."
(http://bioethics.georgetown.edu/nbac/pubs.html "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance", accessed 3/26/02).

Anonymized
Identifying information has been removed and is no longer associated with the information.

The National Bioethics Advisory Committee describes anonymized biological material as "*Unlinked samples:* Sometimes termed "anonymized," these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being."
(http://bioethics.georgetown.edu/nbac/pubs.html "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance", accessed 3/26/02).

Confidentiality
No state law definition. The term is used in the statutes, but is not defined.

Black's Law Dictionary Definition: Entrusted with the confidence of another or with his secret affairs or purposes; intended to be held in confidence or kept secret.

Limited access to or limited disclosure of certain information. Access or disclosure is governed by statute, rule, or case law.

It is not the same thing as privacy or privilege.

De-Identified
HIPAA regulations stipulate that 18 individual identifiers must be removed from health information to 'de-identify' it. These include: name of patient, relatives, or employer; address; all elements of dates (except year) for dates directly related to an individual including birth date, admission date, discharge date, date of death and all ages over 89; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate or license numbers; vehicle identifiers and serial numbers, including license numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including voice and finger prints, full face photographic images and comparable images; any other unique identifying number, characteristic, or code.
(from: Smith, K./Murphy, G., HIPAA policy development guide, University of Washington Health Information Administration, 2001; http://depts.washington.edu/hia).

Deoxyribonucleic Acid (DNA)
No state or federal law defines DNA.

A nucleic acid that constitutes the genetic material of all cellular organisms and the DNA viruses; DNA replicates and controls through messenger RNA the inheritable characteristics of all organisms. A molecule of DNA is made up of two parallel twisted chains of alternating units of phosphoric acid and deoxyribose, linked by crosspieces of the purine bases and the pyrimidine bases, resulting in a right-handed helical structure, that carries genetic information encoded in the sequence of the bases.
(http://www.academicpress.com/inscight/04221999/DNA1.htm, accessed 3/26/02)

Discrimination
Used in statute and case law but does not have a specific definition.

Black's Law Dictionary: ...A failure to treat all alike under substantially similar conditions

Genetic Characteristic
No Washington state or federal law defines 'genetic characteristic'.

South Carolina law (S 535) defines 'Genetic characteristic': Any scientifically or medically identifiable gene or chromosome, or alteration thereof, which is known to be a cause of disease or disorder or determined to be associated with a statistically increased risk of development of a disease or disorder and which is asymptomatic of any disease or disorder.

California law (SB 654) defines "Genetic characteristic": any scientifically or medically identifiable gene or chromosome, or combination or alteration thereof, that is known to be a cause of a disease or disorder in a person or his or her offspring, or is determined to be associated with a statistically increased risk of development of a disease or disorder, or inherited characteristics that may derive from the individual or family member, that is presently not associated with any symptoms of any disease or disorder."

Genetic Discrimination
There is no Washington state law definition

Differential treatment of an individual or class of individuals based on genetic information. Generally used to refer to adverse discrimination in employment or health, life and disability insurance.

Genetic Information
There is no Washington state law definition. Both HIPAA (29 USC Sec. 1181(b)) and WAC 284-43-720 state that 'genetic information' shall not be treated as a pre-existing condition in the absence of a diagnosis of the condition related to such information.

2002 ESSB 5207 adds DNA to the definition of health care information: "Health care information" means any information, whether oral or recorded in any form or medium, that

identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care *including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs*. The term includes any record of disclosures of health care information.

Proposed legislation in Washington state includes the following definitions:

1998 SB 5298: "Genetic information" means information about genes, gene products, or inherited characteristics.

1998 SB 6663: "Genetic information" means information about inherited characteristics. Genetic information can be derived from a genetic test, family history, or medical examination.

2001 SB 5282 & 5283: No use of the term "genetic information" instead focus narrowed to discuss DNA specifically. "screen a person's DNA." "Screening" means obtaining a person's DNA and identifying a sequence of chemical base pairs or interpreting data from DNA analysis.

2001 SB 5665: "Genetic information" means information about genes, gene products, or inherited characteristics, that may derive from an individual or family member of such individual and includes but is not limited to information derived from genetic tests and information about a request for or the receipt of genetic services by such individual or family member of such individual. "Genetic information" also includes information about the occurrence of a disease or disorder in family members.

Other state's definitions and case law definitions include:

Oregon's definition: "Genetic information" means information about an individual or an individual's blood relatives obtained from a genetic test.

South Carolina's definition: "Genetic information" means information about genes, gene products, or genetic characteristics derived from an individual or a family member of the individual. 'Gene product' is a scientific term that means messenger RNA and translated protein. For purposes of this chapter, 'genetic information' shall not include routine physical measurements: chemical, blood, and urine analysis, unless conducted purposely to diagnose a genetic characteristic; tests for abuse of drugs; and tests for the presence of HIV".

Case law: This appeal involves the question of whether a clerical or administrative worker who undergoes a general employee health examination may, without his knowledge, be tested for highly private and sensitive medical and genetic information such as syphilis, sickle cell trait, and pregnancy. Norman-Bloodsaw v. Lawrence Berkeley Laboratory 135 F.3d 1260 C.A.9 (Cal.), 1998.

Genetic Test
There is no Washington state law definition.

President Clinton's Executive Order To Prohibit Discrimination in Federal Employment Based on Genetic Information defines genetic test as: "the analysis of human DNA, RNA,

chromosomes, proteins, or certain metabolites in order to detect disease-related genotypes or mutations. Tests for metabolites fall within the definition of "genetic tests" when an excess or deficiency of the metabolites indicates the presence of a mutation or mutations. The conducting of metabolic tests by a department or agency that are not intended to reveal the presence of a mutation shall not be considered a violation of this order, regardless of the results of the tests. Test results revealing a mutation shall, however, be subject to the provisions of this order.

The Secretary's Advisory Committee on Genetic Testing defines *genetic testing* as "the analysis of chromosomes, genes, and/or gene products to determine whether a mutation is present that is causing or will cause a certain disease or condition. It does not involve treatment for disease, such as gene therapy, although test results can sometimes suggest treatment options." The report also defines *gene testing* as "examination of body fluid or tissue for the presence of altered or abnormal amounts of a protein, chemical, chromosome, or gene that indicate the presence or absence of genetic disease." A definition of *predictive gene tests* is also provided: "Predictive gene tests: tests to identify gene abnormalities in a healthy person that may make them susceptible to certain diseases or disorders."
(http://www4.od.nih.gov/oba/sacgt/gtdocuments.html, Public Consultation on Oversight of Genetic Tests, accessed 3/26/02)

South Carolina law (S 535) defines genetic test as "A laboratory test or other scientifically or medically accepted procedure for determining the presence or absence of genetic characteristics in an individual."

Health Care Information
As defined in the Washington State Uniform Health Care Information Act (RCW 70.02), health *care* information is "any information whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care. The term includes any record of disclosures of health care information".

ESSB 5207 (passed the house and senate in March 2002 – currently pending the governor's signature) proposed a change to this definition. The change is as follows:
"'Health care information" means any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care *including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs.* The term includes any record of disclosures of health care information."

Health Information
As defined in the federal Health Information Portability and Accountability Act (HIPAA), health information is "any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual or the provisions of health care to an individual or the past, present, or future payment for the provision of health care to an individual".

Informed Consent (Health Care)
Not specifically defined but used in statute and case law.

State law: If a patient while legally competent, or his representative if he is not competent, signs a consent form which sets forth the following, the signed consent form shall constitute prima facie evidence that the patient gave his informed consent to the treatment administered and the patient has the burden of rebutting this by a preponderance of the evidence:
(1) A description, in language the patient could reasonably be expected to understand, of:
(a) The nature and character of the proposed treatment;
(b) The anticipated results of the proposed treatment;
(c) The recognized possible alternative forms of treatment; and
(d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment;
(2) Or as an alternative, a statement that the patient elects not to be informed of the elements set forth in subsection (1) of this section.

Failure to use a form shall not be admissible as evidence of failure to obtain informed consent.
RCW 7.70.060

Informed Consent (Research)
Section 46.116 of the Code of Federal Regulations Title 45 describes general requirements of informed consent in research.
(http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm)

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
(2) A description of any reasonably foreseeable risks or discomforts to the subject;
(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent
Set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent

set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

Law
Includes both rules and statutes. Black's Law Dictionary defines law as: "That which is laid down, ordained, or established. That which must be obeyed and followed by citizens, subject to sanctions or legal consequences."

A rule of conduct or action prescribed or formally recognized as binding or enforced by a controlling authority:
a) A command or provision enacted by a legislature, also statute
b) Something (as a judicial decision or administrative rule) authoritatively accorded binding or controlling effect in the administration of justice
(http://www.lawyers.com/lawyers-com/content/glossary/glossary.html accessed 3/26/02)

Privacy
The concept is addressed in statute and case law. Privacy unlike confidentiality is constitutionally based.

A constitutional or common law right to protect information that would be highly offensive to a reasonable person if it was disclosed. Courts have broadly characterized the right to privacy as a right to confidentiality and autonomy-the right to be let alone.

Black's Law Dictionary Definition: Right to privacy: The right to be let alone, the right of a person to be free from unwarranted publicity.

A person's right to keep information about him/self from being disclosed to others.

Regulation
An authoritative rule, specifically a rule or order issued by a government agency and often having the force of law…. An agency is often delegated the power to issue regulations by the legislation that created it. Regulations must be made in accordance with prescribed procedures,

such as those set out in the federal or a state Administrative Procedure Act. (http://www.lawyers.com/lawyers-com/content/glossary/glossary.html accessed 3/26/02).

Rule

A general term, meaning a provision adopted by a governmental entity under the authority granted to the entity by the legislature in statute or the constitution. In Washington State these are called the Washington Administrative Code (WACs). At the Federal level the term is Code of Federal Regulations (CFRs). An example is HIPAA. HIPAA is a federal legislative act, which is codified in statute. Under the statutory authority of HIPAA, the Department of Health and Human Services promulgated a series of rules, one of which is the privacy rule. A rule is enforceable law, however its legal effect may be challenged on a variety of grounds, both procedural and substantive. Black's Law Dictionary definition of rule is: "An established standard, guide, or regulation."